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Can we use routinely collected outcome data for a nationwide trial on venous thromboembolism prophylaxis following primary joint replacement? A feasibility study

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Abstract:	Background UK hospitals nationally report venous thromboembolism (VTE) within 90-days of hospital admission, with Hospital Acquired Thrombosis (HAT) registers at each centre used for this. We assessed the accuracy of our HAT register in identifying VTE following primary THR and TKR. Methods We assessed 982 elective admissions for primary THR and TKR at a large tertiary centre during 2018. The primary outcome was any VTE (DVT and/or PE) within 90-days post-surgery. VTEs were identified by systematically searching hospital databases (including discharge and outpatient letters, readmissions, emergency department visits, and imaging) for every patient. VTEs were also collected using the HAT database at our centre, which is maintained regularly by a specialist nursing team and used to report VTEs nationally. Diagnostic test characteristics were assessed for HAT in identifying VTEs compared to the gold standard (i.e. VTE's from the hospital databases). Results The prevalence of VTE was 2.7% (n=27), with 20 VTEs identified by HAT. The accuracy of HAT in identifying VTEs were: sensitivity=74.1% (95% CI=53.7-88.9%), specificity=100% (CI=99.6-100%), positive predictive value=100% (CI=83.2-100%), negative predictive value=99.3% (CI=98.5-99.7%). Conclusions One-quarter of VTEs occurring after THR and TKR were not identified by the HAT register. These cases would be missing when our hospitals data is sent for national VTE reporting, and therefore would have substantial implications if HAT were primarily used to identify VTEs in a trial. Further work is needed to improve the accuracy of HAT VTE reporting before this could be relied upon in this setting.

Cover letter

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Title: Can we use routinely collected outcome data for a nationwide trial on venous thromboembolism prophylaxis following primary joint replacement? A feasibility study

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IRB approval: The study was approved by the institutional review board (CA25999).

All of the aforementioned authors have actively participated in the study, and the work has not been submitted elsewhere for consideration for publication.

Dr John J. Callaghan
Editor in Chief
Journal of Arthroplasty

13th March 2020

Dear Dr Callaghan,

Re: "Can we use routinely collected healthcare data for a nationwide trial on venous thromboembolism prophylaxis following primary joint replacement? A feasibility study"

(JOA-D-19-02075)

We are very grateful for the opportunity to revise the above manuscript and we thank the Editor and the Reviewers for their constructive comments, which we believe have helped improve the manuscript.

We have responded to the specific comments below and made revisions accordingly in the manuscript. We have provided one clean copy of the manuscript as requested. Details are provided below.

We have submitted and formatted our paper as a "Brief Communication" article for the journal. The instructions on the journal website for this type of piece are as follows:

Brief Communications are meant to be reports that promptly disseminate new ideas and observations. These ideas may not be sufficiently mature or evaluated to merit publication as a full manuscript and yet may be of interest and importance. An example would be the report of a group of catastrophic failures of a new implant design that would serve as an early warning to the readership. Brief Communications will be limited to 2 printed pages, including text, tables, figures, and references. This corresponds to 6 double-spaced standard manuscript pages, with 1 page of text eliminated for every figure or table added. References should be limited to less than 10. In addition, the standard complete format for papers—introduction, materials and methods, results, and discussion—may be eliminated; however, please include a brief abstract. Brief Communications will be reviewed as soon as possible and, when accepted, published in the next possible issue.

We believe the topic and content of our paper is well suited for a Brief Communication article. However we consider that a number of the comments made by Reviewer 2 (below) are beyond the scope of this article type given the tight constraints on word count and formatting for a Brief Communication article, so we have regrettably been unable to action all of these changes comprehensively in the revised manuscript. However we have done our best to answer the questions raised in the response letter, and where space permitted included these in the revised manuscript. We hope that these responses will be suitable given the paper has been submitted as a Brief Communication article.

Response to reviewer comments

Reviewer Number 1:

1. **This brief communication reported the accuracy of the HAT register in identifying VTE following primary THA and TKA. The results showed one-quarter of VTES were not identified by the HAT**

register. I think this manuscript is good and reflects the real situation when we use the data from some big databases. This manuscript is good English writing and easy to read.

We thank reviewer 1 for their kind comment.

2. **The only thing I want to mention is, according to the study, 7 VTEs were missed by HAT. Could the authors analyze the reasons for the 7 cases of missing? If possible, a table for each case is better. I think this might help the readers know more about the real situation if they want to get data from the HAT register.**

Many thanks for this suggestion. As this is a Brief Communication article we have elected to add some text about why the 7 cases where missed (page 5, lines 95-98), rather than a table which removes a page of space in the manuscript as per the journal instructions. We have also discussed the missing cases when considering mechanisms for quality improvement of the HAT register at our hospital (page 7, lines 139-140).

Reviewer Number 2:

Recommendation:

3. **This is a very interesting paper. It shows one of the important weaknesses of registries and other large administrative databases which is data entry. All of these registries require quality of data assessment to ensure that all the data is entered accurately and not missed. This means that the papers that might have used HAT register only, might not represent the accurate data. I recommend revision to provide more details as well as clarifications.**

We thank reviewer 2 for their kind comment.

4. **Please provide your hypotheses at the end of the introduction section**

We have now added our hypothesis at the end of the introduction section (page 3, lines 61-62).

5. Please provide the reason you chose to review 982 patients? How did you calculate your sample size?

This was a sample size of convenience as it included all primary hip and knee arthroplasty patients over a one-year calendar period (2018) treated at our centre. The authors considered this sample size provides the paper with sufficient numbers to undertake the proposed work, as we needed to ensure there were going to be sufficient numbers of outcome events (i.e. VTEs) for assessment. However we believe that a formal sample size calculation is beyond the scope of this feasibility work on the use of a routinely collected dataset for potential future outcome assessment in a trial and for the limits imposed by the instructions for a "Brief Communication" article (see journal instructions for this type of article above on page 1).

6. **Please provide the study purpose and study hypotheses at the end of the introduction section.**

We consider that the first 2 paragraphs of the introduction set the background and purpose of the work. However if the reviewer has any specific comments on how to improve on this whilst keeping

the paper in the "Brief Communication" article format and tight limits, then we would be happy to make subsequent alterations to this section. As per our response to reviewer comment 4, we have added a formal hypothesis as requested.

7. Are you comparing 2 HAT databases, one local and one national? Please clarify.

We are only assessing the accuracy of our local HAT database at our centre. How the HAT database functions at our centre is described (page 4, lines 78-85). This local HAT database is being compared to the existing "gold-standard" of systematic searches of all medical records available for all patients who underwent arthroplasty at our centre during the study period (details on page 4, lines 69-76).

There is no distinct and separate national HAT database. The VTE rates at 90-days from local HAT databases are submitted to national authorities, with our data then combined with data from other local HAT databases at other hospitals to give a national VTE rate across all hospitals (note that we do not have access to these national VTE rates, or rates at other hospitals). We have made changes in the text to emphasise the process (see above pages/lines cited in this response).

8. If you are comparing your hospital HAT register with local or national HAT register: has your hospital HAT register been quality checked? You mention your hospital database as gold standard. How do you know your hospital database is accurate?

Please see our response to reviewer comment 7 which addresses most of these issues. The current piece of work was conducted to assess the quality of data in our hospital HAT register in comparison to the existing alternative mechanism for data collection which involves screening of all available data sources within the unit to identify detected events. We point out in the introduction that the accuracy of HAT registers at any hospital is unknown (page 3, line 58), therefore we feel this is an important piece of work given the drive to use data from registers for outcomes assessment in research, including trials. We do not know the accuracy of our "hospital database", which included all available sources (discharge and outpatient letters, electronic records, readmissions, emergency department visits and imaging) for every patient. These are all the clinical records available for every patient consultation/event in the hospital, which we would expect to be accurate as they are used for routine clinical care on a daily basis. However this would be difficult to check as it is not clear what the "gold-standard" would be such a case, unless a formal large cohort study was performed which would require the use of invasive testing such as venogram to determine the absolute rate and hence be very expensive, time-consuming and associated with risk. We have already highlighted potential limitations with both HAT and our hospital database in the discussion (page 6, lines 127-129).

9. If this HAT register is national or at least multicenter, could it be possible that your data abstracters who enter the data to the HAT register are the reason for inaccuracy and other hospitals are doing better? Have you had a chance to compare your hospital data with others?

This is a local HAT register so the issue regarding data abstracters is not relevant. We have not had chance to compare our hospital data with others, as the accuracy of HAT registers at any hospital is currently unknown.

10. How did you identify the patients in the database and HAT register? CPT/ICD-9 code…? Could it be possible that the data was entered correctly but the codes used to find the patients were wrong?

Details of how patients with VTEs were identified are described, and have now been expanded (page 3, lines 69-85). CPT/ICD-9 codes were not used hence we believe that this will not have introduced bias into our study.

11. Please clarify the routine diagnostic process for diagnosis of VTE in your hospital. Did you consider very small subsegmental PEs positive for VTE?

We have clarified the investigations used for diagnosing VTE, which would extend to include subsegmental PEs (however none of the PEs identified were very small subsegmental) (page 3, lines 73-75). However given this is a "Brief Communication" article we do not have the space to provide more details about the routine diagnostic process for VTEs at our hospital.

12. If the HAT register that you investigated is multicenter or national register, has it been quality checked before? If yes, this has to be mentioned in the introduction and also discussion.

As per above responses, the HAT register was local. In the introduction we have highlighted the fact that the accuracy of HAT registers at any hospital is currently unknown (page 3, line 58).

13. You need to add a dedicated statistical analysis section. You need to have hypotheses mentioned in the introduction section

A dedicated statistical analysis section is beyond the scope of the work required for a "Brief Communication" article (see journal instructions for this type of article above on page 1, and also previous "Brief Communication" articles published in the journal). However we have expanded the last paragraph of the Methods section (page 5, lines 87-91) to highlight exactly what was done from a statistical analysis aspect. We feel this is sufficient given this is essentially an analysis of diagnostic test characteristics using a two by two table, which can be performed relatively simply. Please see our response to reviewer comment 4 regarding the addition of a study hypothesis.

14. What analysis methods did you use? Please provide details and rationale.

Please see our response to reviewer comment number 13 above. Diagnostic test characteristics is the accepted method of assessing the accuracy of one test/method against what is considered a "gold-standard" test/method.

15. How did you calculate your sample size?

Please see our response to reviewer comment 5 above. We believe that a formal sample size calculation is beyond the scope of the work required for a "Brief Communication" article (see journal instructions for this type of article above on page 1).

16. You have 2 independent investigators. How did you compare their results to ensure they match?

We have now made it clear that between 2 investigators all records were reviewed, however there was no overlap (i.e. the same record being reviewed by both investigators) (page 4, lines 71-73). This decision was taken given the need to balance the workload (as a vast number of records/hospital databases needed to be reviewed for nearly 1000 patients) and in light of the outcome being assessed (which was a categorical diagnosis of VTE recorded in imaging reports or official/formal hospital documentation). We recognise this is a limitation and have highlighted this in the Methods (page 4, lines 71-73), however we consider formal assessment of inter-observer reliability to be

outside the scope of a “Brief Communication” article given the reasons cited above to complete this piece of work.

17. Please provide more details about the plans for HAT register data quality improvement. Some details about the papers published using this register is also important. These papers (if any) might need to be retracted etc if the quality of their data was low.

We have now expanded on our quality improvement plans as much as we can (which include highlighting specifically why the cases were missing from the HAT database), whilst keeping in mind this is a “Brief Communication” article (page 7, lines 138-145). We have added a reference (number 11) to the only paper we are aware of which uses HAT data following joint replacement, and have highlighted caution with interpretation of this paper given our findings (page 6, lines 132-136).

We hope that these responses meet with your approval and that you will now consider the manuscript for publication in ‘The Journal of Arthroplasty’.

With kind regards

Yours sincerely

The authors

Can we use routinely collected outcome data for a nationwide trial on venous thromboembolism prophylaxis following primary joint replacement? A feasibility study

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Can we use routinely collected healthcare data for a nationwide trial on venous thromboembolism prophylaxis following primary joint replacement? A feasibility study

Abstract

Background

UK hospitals nationally report venous thromboembolism (VTE) within 90-days of hospital admission, with Hospital Acquired Thrombosis (HAT) registers at each centre used for this. We assessed the accuracy of our HAT register in identifying VTE following primary THR and TKR.

Methods

We assessed 982 elective admissions for primary THR and TKR at a large tertiary centre during 2018. The primary outcome was any VTE (DVT and/or PE) within 90-days post-surgery. VTEs were identified by systematically searching hospital databases (including discharge and outpatient letters, readmissions, emergency department visits, and imaging) for every patient. VTEs were also collected using the HAT database at our centre, which is maintained regularly by a specialist nursing team and used to report VTEs nationally. Diagnostic test characteristics were assessed for HAT in identifying VTEs compared to the gold standard (i.e. VTE's from the hospital databases).

Results

The prevalence of VTE was 2.7% (n=27), with 20 VTEs identified by HAT. The accuracy of HAT in identifying VTEs were: sensitivity=74.1% (95% CI=53.7-88.9%), specificity=100%

(CI=99.6-100%), positive predictive value=100% (CI=83.2-100%), negative predictive value=99.3% (CI=98.5-99.7%).

Conclusions

One-quarter of VTEs occurring after THR and TKR were not identified by the HAT register. These cases would be missing when our hospitals data is sent for national VTE reporting, and therefore would have substantial implications if HAT were primarily used to identify VTEs in a trial. Further work is needed to improve the accuracy of HAT VTE reporting before this could be relied upon in this setting.

Key words

hospital acquired thrombosis; total hip replacement; venous thromboembolism; validation

Introduction

Over 200,000 total hip and knee replacements (THR and TKR) are performed annually in the UK.[1, 2] These patients are at risk of venous thromboembolism (VTE), which is associated with mortality, significant morbidity and healthcare costs.[3] Almost all patients receive chemical VTE prophylaxis for up to 6-weeks postoperatively,[4,5] although the optimum thromboprophylactic agents remain unknown. NICE recommends numerous options with equal weighting, including low-molecular weight heparin (LMWH), aspirin (with or without LMWH) and newer direct oral anticoagulants (rivaroxaban, apixaban, dabigatran).[4] Level 1 evidence to support selection of VTE prophylaxis is lacking, so NICE have recommended large multi-centre randomised controlled trials (RCTs) are needed to assess clinical and cost-effectiveness.[4] RCTs are difficult given the need for large sample sizes,[6] the low 90-day VTE event rate (1-2%)[7] and the cost and complexity of running such large trials.

Outcomes could be obtained using routinely collected healthcare datasets. This would substantially reduce costs and increase feasibility for trials comparing VTE prophylaxis. For example, the NHS has a national mandatory register for surgical site infection within 30-days of orthopaedic surgery, with this data used to drive quality improvement.[8] NHS hospitals must report all VTEs within 90-days of hospital admission to their Clinical Commissioning Group (CCG) quarterly, which are subsequently submitted to Public Health England. Hospital Acquired Thrombosis (HAT) registers at each individual hospital were developed for this purpose. However the accuracy of the HAT registers at any hospital is unknown.

We assessed the accuracy of our institutions HAT register in identifying VTEs following THR and TKR. Our null hypothesis was that there was no difference between the VTE events identified in the HAT register compared with the actual reported VTE events at our hospital.

Methods

We reviewed all elective primary THR and TKR admissions at a UK tertiary centre between 1st January 2018 and 31st December 2018. 982 joint replacements were eligable, consistent with nationally submitted data.[1, 9] The primary outcome was any VTE (deep vein thrombosis and/or pulmonary embolism) within 90-days following surgery, as recommended by NICE.[4]

VTE events within 90-days of surgery were identified by systematically searching all hospital databases (discharge and outpatient letters, electronic records, readmissions, emergency department visits and imaging) for every patient. Between two authors, all records were reviewed. However authors did not review the same records so no formal inter-observer reliability assessment was performed. Authors recorded all confirmed imaging evidence of any VTEs regardless of symptoms (computerised tomography pulmonary angiography and/or venous ultrasonography), and any VTEs detailed on patient letters and electronic records. Both authors were blinded to HAT data.

VTEs occurring at our centre were also collected using the hospitals local HAT database (started in 2014), with this data subsequently submitted to inform national VTE rates. Patients presenting and/or admitted with VTEs within 90-days of any hospital admission were identified by specialist nurses from two-weekly data extracts, provided by Information Analysts at the hospital, of all VTEs occurring following any admission. The HAT database is maintained regularly, and a root cause analysis is performed for all VTEs. We used any VTE recorded in HAT during the study period and within 90-days following the study end date (i.e. after 31st December 2018).

VTE events recorded from HAT were cross-referenced with those collected from the hospital database searches, and a two-by-two contingency table was constructed. Diagnostic test characteristics (sensitivity, specificity, positive and negative predictive values) were then calculated (with 95% confidence intervals (CIs)) for the HAT register in identifying VTEs compared to the current standard (VTE's from the systematic hospital database searches).

Results

The prevalence of VTE from the hospital database search was 2.7% (n=27). Twenty of these VTEs were identified by HAT, and HAT did not identify any additional VTEs. Of the 7 cases of VTE missed by the HAT register, 5 were identified from radiological investigations (some during inpatient stays, and some as an outpatient) and 2 were identified from outpatient letters.

The diagnostic test characteristics for the HAT register in detecting VTEs identified by the gold-standard systematic hospital database searches were: sensitivity=74.1% (CI=53.7-88.9%), specificity=100% (CI=99.6-100%), positive predictive value=100% (CI=83.2-100%), and negative predictive value=99.3% (CI=98.5-99.7%).

Discussion

One-quarter of VTEs occurring after joint replacement at our hospital were not identified by the HAT register. This is concerning given our hypothesis, and that HAT data from each hospital is used to report VTE rates nationally. In its current format, the HAT database event rates could not primarily be used for RCT outcome reporting.

Using routinely collected data for outcome assessment in large RCTs has many potential advantages, namely saving money, time, and resources. We have met with our own Patient and Public Involvement group, which included patients with musculoskeletal conditions, to discuss this concept.[10] The group was unanimously supportive towards using routinely collected healthcare data for collecting outcomes in large trials. They felt that if this were shown to be valid compared with more traditional methods (like questionnaires or investigations), this would be preferable for many future studies rather than intensive patient follow-up and/or investigation, but only if the data was reliable.

Contrary to the potential advantages of routinely collected healthcare data for patients, researchers, and clinicians, our institutions HAT database is not currently accurate enough to be used for reporting VTE outcomes in large RCTs. Although any missing VTE data would likely be missing at random from each intervention arm of any RCT, large centre sample sizes would be required to ensure this, and there is still potential for bias. Such issues must be balanced against the feasibility and cost of doing an RCT with VTEs detected using more traditional consultations and questionnaires. A large ongoing trial of 25,000 patients in the United States has cost over $14 million.[6] A limitation of both the HAT register and our search of local databases, was that we would not be able to identify cases where patients had a VTE treated in another hospital or region. Furthermore, each hospital locally devised services to collect VTEs for the HAT register given that CCGs do not specify how to do this. Therefore there will be variability between the quality of HAT registers between hospitals, which will have implications for accuracy and data quality. However our findings do now question the accuracy of previous reports that have relied on HAT registers to identify VTEs following arthroplasty,[11] and findings from these previous studies must be interpreted with

caution until the respective centres have assessed the accuracy of their own HAT registers for VTE reporting.

We have used our findings to drive quality improvement locally for our HAT register. After investigating reasons for HAT missing 7 VTEs (including 5 missed from radiological investigations) we have proposed improvements in discharge letters (i.e. documenting any inpatient investigation of VTEs regardless of if they were negative or not treated; and clearly stating when aspirin discharge prescriptions are for VTE prophylaxis rather than being assumed to be for analgesia/pre-existing conditions), and also routinely searching all imaging within 90-days of joint replacement. We plan to reassess the accuracy of our hospitals HAT database in due course to assess for quality improvement.

Conclusions

One-quarter of VTEs occurring after primary THR and TKR were not identified by the HAT register. These cases would be missing when our hospitals data is sent for national VTE reporting. Therefore this would have substantial implications if HAT was primarily used to identify VTE events in RCTs, and any future study relying on this should validate outcome capture as we have done here. Further work is needed to assess, and if needed improve, the accuracy of HAT registers at many hospitals for VTE reporting before this could be relied upon in multicentre studies.

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Ethical approval: The study was approved by the institutional review board (CA25999).

Data sharing: This can be done on request.